

Appl. No. 10/750,428  
Amdt. Dated June 30, 2005  
Reply to Office Action of March 31, 2005

Attorney Docket No. PA094-US  
Customer No.: 27405

REMARKS/ARGUMENTS:

Claims 1 and 14 are amended. Claims 1-28 are pending in the application. Reexamination and reconsideration of the application, as amended, are respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, first paragraph:

Claims 1-28 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

The Examiner states,

"As to claims 1 and 14, what single 'material' (line 2 from last of claims 1 and 14) has a 'plurality' (line 2 from bottom of claims 1 and 14) of viscosity values at the same time? Is the same material treated in some fashion to change the viscosity (which would likely result in a different material), or are different materials used to vary the viscosity of the fluid employed in the system. At present, it is even unclear, as 'materials' (p. 68, line 14) seems to suggest different materials, and yet 'varying' (p. 68, line 14 seems to suggest the same material. Which ever it might be, please provide a showing of support for either of the two possibilities."

The Examiner further states that "material" is not expressly listed as a limitation in the system claim. The Applicant respectfully traverses this rejection.

Claim 1, as amended, is as follows:

A system for evaluating or calibrating a bubble detector, comprising:

a conduit adapted to pass a flow material therethrough, wherein the conduit is configured for passing flow materials of different viscosities;

a pump operatively coupled to the conduit to pump the flow material through the conduit;

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a bubble-forming device operatively coupled to the conduit, the bubble-forming device being adapted to introduce bubbles into the flow material passing through the conduit; and

a bubble detector to be evaluated positioned to examine the bubbles in the flow material passing through the conduit.

Claim 1, as amended, clarifies that the conduit is configured for using flow materials of different viscosities. Hence, it is only one material at a time that is being used and that one material has only one viscosity. Support for this interpretation can be found at page 67, lines 21-23 and page 68, lines 15-18 of the Applicant's specification which states, "Typically, the viscosity of the flow material 1112 used for evaluation is comparable with the viscosity of the material utilized in the operational environment, e.g., blood mixed with gas-enriched physiologic fluid in this example." Thus, there is only one flow material used and the flow material that is chosen has a viscosity which is comparable to the material utilized in the operational environment.

In light of the foregoing, Applicant respectfully submits that claim 1 is enabled. Claims 2-13 depend from claim 1 and are similarly enabled. Withdrawal of this rejection is thus respectfully requested.

In addition, "wherein the conduit is configured for using flow materials of different viscosities" is a positive limitation as it defines a feature of the system that needs to be present.

Claim 14, as amended, similarly states that the conduit is configured for using flow materials of different viscosities. Consequently, claim 14 and its dependent claims 15-28 are clear and enabled for the reasons discussed above. Withdrawal of this rejection is thus respectfully requested.

CLAIM REJECTIONS UNDER 35 U.S.C. § 112, second paragraph:

Claims 1-28 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The Examiner states,

"As to claims 1, 14, 'flow *material* is capable of having a *plurality* of material viscosities' (italics added, last two lines of each claim) is not consistent with the originally filed disclosure."

As discussed above, claims 1 and 14 were amended to clarify that it is only one material at a time that is being used and that one material has only one viscosity. Also, as discussed above, support for these amendments can be found at page 67, lines 21-23 and page 68, lines 15-18 of the Applicant's specification.

In light of the foregoing, claims 1 and 14, and their respective dependent claims 2-13 and 15-28, are not indefinite. Withdrawal of this rejection is thus respectfully requested.

**CLAIM REJECTION UNDER 35 U.S.C. 103:**

Claims 1-5, 8, 9, 11-15, and 17-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over either Gilcher et al. or Natwick et al., and further in view of Kline-Schoder et al. The Applicant respectfully traverses this rejection.

Applicant respectfully submits that the cited references cannot render claim 1 obvious because the cited references fail to teach or suggest a system that has both a bubble-forming device and a bubble detector to be evaluated positioned to examine the bubbles in the flow material passing through the conduit, wherein the conduit is configured for using flow materials of different viscosities.

Flow materials of varying viscosity may be utilized and may include newtonian or non-newtonian fluids. It is the discovery of the present invention that the flow material to be evaluated be comparable with the viscosity of the material utilized in the operational environment, e.g., blood mixed with gas-enriched physiologic fluid. (Applicant's specification, at page 68, lines 6-18). On the other hand, as noted by the Examiner, Kline-Schoder is limited to a water environment. Accordingly, bubbles are produced by directing compressed air through a glass tube in a water tank. (Kline-Schoder, column 15, line 56-column 16, line 12; Figure 13). Therefore, the simulation of operational environments made possible with the present invention

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would not be able to occur, since Kline-Schoder lacks the flexibility to accommodate different flow materials.

Gilcher and Natwick cannot remedy the defect of Kline-Schoder and are not relied upon by the Examiner for such. Instead, the Examiner cites Gilcher and Natwick for teaching that bubble detectors may be calibrated to respond to a particular size. However, the Examiner acknowledges that Gilcher and Natwick fail to provide particulars of calibration device to provide a standard, and do not refer to different viscosities.

The Examiner apparently acknowledges that Kline-Schoder is limited to a water environment. However, the Examiner states that the "plurality of material viscosities" is in error and therefore, apparently has not given any patentable weight to this limitation. In addition, as discussed above, the Examiner states that "material" is not expressly listed as a limitation in the system claim.

The Applicant, as discussed above, amended claims 1 and 14 to satisfy enablement and indefiniteness issues. In addition, present claims 1 and 14 use the language "wherein the conduit is configured for using flow materials of different viscosities". Therefore, the feature relied upon by the Applicant should be regarded as a limitation.

In light of the foregoing, Applicant respectfully submits that the cited references could not have made claim 1 obvious, because the combination of references fails to teach or suggest each and every claim limitation. Claims 2-5, 8, 9, and 11-13 depend from claim 1 and cannot be made obvious for at least the same reasons as claim 1. Withdrawal of this rejection is thus respectfully requested.

Claim 14, as discussed above, was similarly amended to satisfy any outstanding enablement and indefiniteness issues, as well as to ensure the feature relied upon by the Applicant is expressly listed as a limitation. Consequently, claim 14 and its dependant claims 15 and 17-28 are patentable over the cited references for the reasons discussed above. Withdrawal of this rejection is thus respectfully requested.

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

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If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1769.

Respectfully submitted,

Date: 6/30/05

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